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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,036	09/09/2003	David J. FitzGerald	015280-361200US	3296

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EXAMINER

BOESEN, AGNIESZKA

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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01/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/659,036	Applicant(s) FITZGERALD ET AL.	
	Examiner Agnieszka Boesen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 12-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/31/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

It is noted that Applicant indicated claim 27 as being withdrawn. However claim 27 was examined in the Office action of June 7, 2007 and is presently under examination.

Applicant's IDS filed October 31, 2007 has been considered.

Election/Restriction

Upon further consideration claims 19, 25, and 26 drawn to the species of the present invention (as previously indicated in the Office action of June 7, 2007) are rejoined.

Claims 1-7, 12-27 are under examination.

Claim Rejections - 35 USC § 112

Rejection of claims 1-7, 12-18, 20-24, and 27 under 35 U.S.C. 112, first paragraph is **withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 103

Rejection of claims 1-7, 12-15, 18, 20-24, and 27 under 35 U.S.C. 103(a) as being unpatentable over Cryz et al. (Vaccine, 1995) as evidenced by Cryz et al. (Infection and Immunity, 1986) in view Pastan et al. (U.S. Patent 5,328,984) and Bukawa et al. (Nature Medicine, 1995) is **withdrawn** in view of Applicant's amendment to the claims and arguments.

Art Unit: 1648

Rejection of claim 16 under 35 U.S.C. 103(a) as being unpatentable over Cryz et al. (Vaccine, 1995) as evidenced by Cryz et al. (Infection and Immunity, 1986) in view Pastan et al. (U.S. Patent 5,328,984) and Bukawa et al. (Nature Medicine, 1995) as applied to claim 1 and further in view of Cardy et al. (WO95/31483 of record in IDS of 7/7/2006) is **withdrawn** in view of Applicant's amendment to the claims and arguments.

Rejection of claim 17 under 35 U.S.C. 103(a) as being unpatentable over Cryz et al. (Vaccine, 1995) as evidenced by Cryz et al. (Infection and Immunity, 1986) in view Pastan et al. (U.S. Patent 5,328,984) and Bukawa et al. (Nature Medicine, 1995) as applied to claim 1 and further in view of Roberge et al. (Journal of Immunology, 1989, Vol. 143, p. 3498-3502) is **withdrawn** in view of Applicant's amendment to the claims and arguments.

New Rejection

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, and 12-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,314,632 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present process claims are obvious over the patented product claims.

Claims 1-12 of the issued Patent 7,314,632 B1 are drawn to the product of the non-toxic *Pseudomonas* exotoxin immunogen comprising: (1) a cell recognition domain; (2) a translocation domain comprising an amino acid sequence at least 95% identical to the sequence of *Pseudomonas* exotoxin A (PE) (SEQ ID NO: 2) from amino acid position 280 to amino acid position 344 thereof and wherein the domain effects translocation to the cytosol; (3) an epitope domain comprising amino acid sequence between about 5 and about 350 amino acids in length that comprises one cysteine loop wherein the loop encodes an epitope of a pathogen and wherein the epitope is non-native to PE domain Ib; and (4) an ER retention domain.

The present claims are drawn to a method of eliciting secretory IgA-mediated immune response to an epitope in a subject by administering a non-toxic *Pseudomonas* exotoxin-A chimeric immunogen as described in claims 1-12 of the issued Patent. The present method claims are obvious over the patented product claims because they are related inventions: product and process of using that product.

The Office notes that the product and the method claims in the Application number 09/462,682 of the issued Patent 7,314,632 B1 were not subject to restriction requirement i.e. the product and the method claims were grouped in one group and examined together (see Restriction requirement of June 8, 2001 in Application 09/462,682).

Thus because the present process claims are obvious over the patented product claims, and because no restriction requirement was made by the Office, the present claims are rejected under on the ground of nonstatutory obviousness-type double patenting (see MPEP 821.04).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 1-4-2008
Primary Examiner, TC1600